

REMARKS/ARGUMENTS

Claims 11 and 18 have been amended to correct a typographical error.
Claims 14 and 19 have been amended to clarify that an effective dissociation reversing amount of an opiate antagonist is administered in accordance with the claimed method.
No new matter is introduced by these amendments.

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Number 6,034,091 (Dante) or U.S. Patent Application Pub. 2002/0091075 (Carlezon, Jr.). Since the cited prior art fails to disclose limitations of the claims and fails to provide any reasonable expectation of success in practicing the claimed invention, the rejection is respectfully traversed.

The claims, as amended, recite administering "an effective dissociation reversing amount of an opiate antagonist" as part of the claimed method for treating refractory depression characterized by dissociation. The Office Action states that "the use of opiate antagonists for treating refractory depression was well-known at the time of applicant's invention" and "one skilled in the art would have been motivated to treat the subtype of dissociation-characterized depression therewith." Office Action at 2. According to the Office Action, Dante teaches the use of opiate antagonists for treating refractory depression.

However, Dante fails to teach or suggest administering an effective dissociation reversing amount of an opiate antagonist to a patient in need as recited in Applicant's claims. The portion of Dante cited in the Office Action (columns 2-3) refers to several depression-related illnesses that can be treated using a combination of anti-depressants and opioid antagonists. Notably, dissociation-related conditions are nowhere to be found in Dante at columns 2-3 or anywhere else. Dante also fails to teach

or suggest a dissociation reversing amount of an opiate antagonist and instead provides a general dosage range, referring the reader to the Physicians Desktop Reference for detailed information. This is not surprising since Dante is not even directed to treatment of dissociation-related disease. In contrast, the present application provides several examples of dosage ranges and regimens for opiate antagonists in general and for particular examples of opiate antagonists. See, e.g., Specification at 15-16.

Dante also fails to teach how to identify a “patient in need” as recited in Applicant’s claims. A patient in need is a patient “with refractory depression characterized by dissociation.” Dante does not contain a single word about how to identify a patient in need. In contrast, the present application teaches how to diagnose a patient with refractory depression characterized by dissociation. See, e.g., Specification at 11-15.

Furthermore, Dante does not provide an reasonable expectation of success regarding treatment of refractory depression characterized by dissociation. Dante provides no clinical guidance or evidence whatsoever for treating depression characterized by dissociation with opiate antagonists. There is simply no basis or indication in Dante that such a treatment would be successful.

According to the Office Action, the Carlezon, Jr. reference “teaches the use of kappa opioid antagonists for treating of depression. As with Dante, Carlezon, Jr. does not teach or suggest identifying a patient in need of treatment for refractory depression characterized by dissociation or an effective dissociation reversing amount of an opiate antagonist. In addition, Carlezon, Jr. does not teach administering both an opiate antagonist and an anti-depressant as recited in Applicant’s claims. Carlezon, Jr. fails to provide any reasonable expectation of success in practicing the claimed invention because it provides only experimental data derived from animal studies.

Application No.: 09/925,190
Amendment dated May 20, 2003
Reply to Office Action of March 27, 2003

Docket No.: G5072.0001/P001

Since there is no animal model for dissociation in human beings, the data in Carlezon, Jr. is not remotely predictive of the effect of a combination of opioid antagonist and antidepressants in humans. Thus, Carlezon, Jr., alone or in combination with Dante, fails to teach all the limitations of the claims or provide any reasonable expectation of success in practicing the claimed invention.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If the Examiner should believe that anything further may be required to place this application in even better form for allowance, he is cordially invited to telephone the undersigned attorneys for Applicants.

Dated: May 20, 2003

Respectfully submitted,

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